

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC)
and Drug Safety & Risk Management Advisory Committee (DSaRM)
September 23, 2009

The committee will discuss new drug application (NDA) 21-217, EXALGO (hydromorphone HCl), Neuromed Pharmaceuticals, Inc., and its safety for the proposed indication of treatment of moderate-to-severe pain in opioid tolerant patients

Draft Questions to the Committee

1. Discuss where Exalgo lies in the spectrum of risk for abuse, including abuse-related overdose and death, compared to other opioid drug products.
2. Based on your assessment of the risk associated with abuse of Exalgo, discuss which of the following options would be appropriate for risk management:
 - a. A program similar to Onsolis, including registration for physicians and patients
 - b. An opioid class-like program including physician education and registration, but no patient registry and, in the short term, an interim REMS pending the larger opioid class program as was done with Embeda
 - c. A unique program